UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

Todd Schueneman, Plaintiff, vs. Arena Pharmaceuticals, Inc. et al., Defendants.	CASE NO. 10cv01959-CAB (BLM) ORDER GRANTING MOTION TO DISMISS WITHOUT PREJUDICE and DENYING MOTION TO STRIKE AS MOOT [Doc. Nos. 44, 45, 47]

Before the Court is Defendants' Motion to Dismiss Consolidated Amended Class Action Complaint [Doc. Nos. 44, 45]. Upon consideration of the briefing, the motion is **GRANTED WITHOUT PREJUDICE**.

I. BACKGROUND

The Consolidated Amended Class Action Complaint (the "Complaint") alleges that Arena Pharmaceuticals, Inc. ("Arena" or the "Company") and its most senior executives violated Section 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act") and Rule 10b-5 promulgated thereunder by making materially false statements and/or omitting to disclose material facts concerning the safety of lorcaserin, Arena's most important developmental drug.[1]

[1] The "Defendants" are Arena; Jack Lief ("Lief"), Arena's President, CEO and Chairman; Robert E. Hoffman ("Hoffman"), Arena's CFO; Dominic P. Behan ("Behan"), Arena's Senior Vice President and Chief Scientific Officer; William R. Shanahan, Jr. ("Shanahan"), Arena's Senior Vice President and Chief Medical Officer; and Christy Anderson ("Anderson"), Arena's Vice President of Clinical Development.

Lorcaserin is intended for weight loss and maintenance of weight loss, representing "the first in a new class of selective serotonin 2C receptor agonists." [¶44.] Lorcaserin's safety profile was important to investors, in part, because prior FDA-approved diet drugs, including Fen-Phen, were removed from the market after it was shown that they caused heart-valve disease (valvulopathy). [¶48.]

In order to obtain FDA approval to market lorcaserin, Arena needed to demonstrate lorcaserin's safety and efficacy based on nonclinical/pre-clinical animal studies and clinical trials on humans. [¶45.] For example, as part of lorcaserin's new drug application ("NDA") to the FDA, Arena was required to conduct a long-term study of potential carcinogenesis on rats (the "Rat Study"). [¶51.] As pled, the Rat Study was a two year nonclinical/pre-clinical study that commenced in 2007 and was designed to help determine the potential risk that lorcaserin may be toxic or cause cancer in humans.

Plaintiff alleges that unknown to investors, Defendants knew by the beginning of the Class Period (March 17, 2008 through January 27, 2011) that the Rat Study showed that lorcaserin caused cancer. Plaintiff alleges that by late 2007, Defendants learned that the Rat Study showed the following risks: lorcaserin caused tumors in rats, including malignant mammary (breast) tumors in both male and female rats, malignant astrocytomas (brain cancer), squamous carcinomas of the subcutis (skin cancer), malignant schwannomas (cancer of connective tissue surrounding nerves or nerve sheath tissue), liver and thyroid. [¶53.] High percentages (56%-70%) of female rats in the study developed mammary cancer, which was "outside the historical range." [¶¶8-9, 76.][2]

So, by March 2008, Arena is alleged to have notified the U.S. Food and Drug Administration ("FDA") about the Rat Study's data. [¶¶ 8-9, 55, 72.] *See also* 21

Lief, Hoffman, Behan, Shanahan and Anderson are referred to as the "Individual Defendants."

[2] "¶_" refers to paragraphs in the Complaint.

C.F.R. § 312.32(c). In response, the FDA did not halt lorcaserin's ongoing human clinical trials. Rather, the FDA requested bi-monthly updates. [¶ 55.] *See* 21 C.F.R. § 312.32(c)(1)(v)(3) ("FDA may require a sponsor to submit IND safety reports in a format or at a frequency different than that required under this paragraph."). This request was atypical. [¶¶9-10; 76.] Defendants did not publicly disclose facts about the Rat Study or the FDA's request related thereto.

Arena provided the FDA with the requested bi-monthly updates until the conclusion of the Rat Study in March 2009. Because of the ongoing nature of the Rat Study, the bi-monthly updates only included "initial reads" of data, not reviewed by outside pathologists. [¶76.] When Arena submitted its final report to the FDA, it included a peer-reviewed analysis by "three [non-Arena] veterinary pathologists" who concluded there were fewer malignant tumors than Arena initially reported to the FDA. [¶¶ 12, 76.] The Rat Study showed an "apparent increase in aggressiveness of adenocarcinoma in rats administered lorcaserin." [¶74.] Defendants did not publicly disclose these facts to investors at the time.

In December 2009, Defendants filed lorcaserin's NDA, and the FDA appointed the Advisory Committee, comprised of physicians and scientists, to discuss and vote on whether to recommend that the FDA approve lorcaserin. [¶13.] The FDA Advisory Committee was scheduled to meet on September 16, 2010. [¶14.]

In September 2010, investors first learned about the Rat Study data and that this data caused the FDA's Advisory Committee to vote 9-5 against recommending approval of lorcaserin. [¶¶18-20, 67-69, 71.] In October 2010, Arena publicly disclosed that the FDA completed its review of the NDA and found that it could not approve the NDA "in its present form." [¶73.] Defendants explained the FDA's reasons to be, among other things, that the NDA failed to demonstrate that the Rat Study was irrelevant to humans. [¶¶73-76.]

Plaintiff alleges that the negative results of the Rat Study and the FDA's concerns over the rat data constituted material facts that should have been, but were

not, disclosed to investors. Plaintiff alleges that instead of disclosing, Defendants repeatedly falsely represented that lorcaserin was safe and made materially false and misleading representations about non-clinical study results. Plaintiff further alleges that when Defendants' prior misrepresentations were disclosed and became apparent to the market, the price of Arena's securities declined precipitously as the prior artificial inflation came out of Arena's stock price. As a result of their purchases of Arena securities during the Class Period, Plaintiff and other members of the putative class suffered economic loss, *i.e.*, damages under the federal securities laws. [¶¶179-185.]

II. LEGAL STANDARD

Plaintiffs allege that Defendants violated § 10(b) of the 1934 Securities Act, and Rule 10b-5 promulgated thereunder, and that the individual defendants acted as controlling persons of Arena within the meaning of § 20(a) of the 1934 Act. In enacting the Private Securities Litigation Act ("PSLRA"), congress imposed a heightened pleading standard for cases alleging securities fraud, requiring that "the complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts upon which that belief is formed." 15 U.S.C. § 78u-4(b)(1)(B). *In re Cutera Securities Litigation*, 610 F.3d 1103, 1107 (9th Cir. 2010). To meet this standard, "Plaintiffs must allege with particularity both the facts constituting the alleged violation, and the facts evidencing scienter, *i.e.*, the defendant's intention to deceive, manipulate, or defraud." *Id.* at 1107-08, *quoting Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007) (internal quotations omitted). In considering a Rule 12(b)(6) motion to dismiss a § 10(b) action, the Court must, as with any motion to dismiss, accept all factual allegations in the complaint as true. *Tellabs, Inc.*, 551 U.S. at 322.

III. ANALYSIS

Rule 10b-5 makes it unlawful "to make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statement made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5(b). To adequately state a claim under Section 10(b), Plaintiffs must allege: (1) a misstatement or omission (2) of material fact (3) made with scienter (4) on which they relied (5) which proximately caused their injury. *DSAM Global Value Fund v. Altris Software, Inc.*, 288 F.3d 385, 388 (9th Cir. 2002). Defendants challenge the adequacy of the Complaint with regard to elements (1) and (3) above. The Court addresses scienter first.

A. Scienter

To plead scienter, Plaintiff must, as to each act or omission, "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). "[T]he ultimate question is whether the defendant knew his or her statements were false, or was consciously reckless as to their truth or falsity." *Gebhart v. SEC*, 595 F.3d 1034, 1042 (9th Cir. 2010). The PSLRA requires that the Court dismiss the complaint if the Plaintiffs do not meet this standard. 15 U.S.C. § 78u-4(b)(3).

In determining whether Plaintiffs have adequately pled scienter on a motion to dismiss, the Court must 1) accept all factual allegations as true, 2) consider "whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard," and 3) take into account plausible opposing inferences." *Tellabs,* 551 U.S. at 322-23. "To determine whether the plaintiff has alleged facts that give rise to the requisite 'strong inference' of scienter, a court must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff. . . . The inference of scienter must be more than merely 'reasonable' or 'permissible'—it must be cogent and compelling, thus strong in light of other explanations. A complaint will survive, we

hold, only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* at 323-24.

Here, Plaintiff argues that Defendants made statements about lorcaserin intended to deceive or with deliberate recklessness as to the possibility of misleading investors. Plaintiff identifies three categories of purported materially false and misleading statements: (1) representations concerning lorcaserin's safety, including statements that lorcaserin was different from current and developmental diet drugs because it is both safe and effective (¶¶84, 95, 97, 99, 103, 105, 108, 110, 113, 115, 118, 120, 132, 134, 136, 141, 144, 146, 148, 152, 154, 156, 167); (2) representations concerning the results and progress of Defendants' non-clinical animal safety studies on lorcaserin, including the carcinogenicity studies like the Rat Study (¶¶86, 89, 92, 97, 99, 120, 128, 138, 156, 159, 173); and (3) certifications signed by Hoffman and Lief that represented Arena's periodic SEC filings (10-Ks and 10-Qs) did not contain any untrue statements of a material fact or omit a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading (¶¶87, 90, 93, 100, 111, 139, 157, 160).[3]

Plaintiff argues that Defendants knew or consciously disregarded the danger that the above statements would mislead investors because the statements omitted the following facts:

(i) that by late 2007, Defendants learned that the findings of the Rat Study included mammary tumors (¶¶ 8, 53-54);

(ii) that in approximately March 2008, Defendants alerted the FDA of the adverse findings from the Rat Study and the FDA instructed that Arena provide

[3] Plaintiff's opposition also identifies representations concerning Defendants' "end-of-review" meeting with the FDA in December 2010 as a fourth category of false statements. However, the Court declines to analyze scienter for the fourth category of statements because there is no factual support for the allegation that defendants omitted information about their "end of review" meeting. As pled, the allegedly omitted information was not learned by Defendants until "[s]ubsequent to the end-of-review meeting." [¶ 79.]

updates every two months to the FDA, an unusual request that is not part of the normal FDA process for development of new drugs (¶¶ 8-9, 55-56, 72, 76);

(iii) that starting in March 2008, Arena provided bi-monthly updates to the FDA on the Rat Study (¶¶ 9, 56, 76);

(iv) that Defendants were not able to demonstrate to the FDA that the Rat Study results were irrelevant to humans (¶¶ 9-10, 57, 76); and

(v) by March 2009, the Rat Study was concluded and in or around March 2009 Defendants sent the final report to the FDA concerning the results of the Rat Study. The final report's results changed prior findings regarding mammary tumors. Specifically, the number of benign mammary tumors increased and the number of malignant tumors decreased (¶¶ 11-12, 58,76).

Therefore, according to Plaintiff, scienter is demonstrated because Defendants knew or were deliberately reckless in not knowing about the Rat Study data and Arena's communications with the FDA about it.

As an initial matter, the Court is not persuaded that the Complaint sufficiently pleads each Defendant knew or were deliberately reckless in not knowing about the Rat Study data or Arena's communications with the FDA about it. Lorcaserin was Arena's core product. Defendants were focused on the development of lorcaserin, they discussed lorcaserin in every conference call, press release and periodic report filed by Arena with the SEC, and nearly all of the Company's resources were dedicated to lorcaserin's development. [*See* ¶34.] However, the facts presently before the Court do not warrant the application of the "core operations" scienter theory, wherein may be inferred that facts critical to a business's "core operations" or important transactions are known to key company officers. *See South Ferry LP, #2 v. Killinger*, 542 F.3d 776, 784-85 (9th Cir. 2008).

Indeed, allegations suggesting a core operations inference, standing alone, will generally not support a strong inference of scienter absent "additional detailed allegations about the defendants' actual exposure to information." *Id.* at 784. Here,

there are no detailed allegations showing how each Defendant would have been exposed to the Rat Study data or FDA communications about it. The Complaint's generic conclusions are insufficient – that based on the defendants' "positions" at Arena each "received and/or had access to data concerning lorcaserin, including the results of the Rat Study." [*See* ¶¶ 40, 42.] Without details showing how each Defendant's job responsibilities or interactions with others would have put them on notice of the omitted facts, there is no factual basis for the Court to begin its scienter analysis.

Where unusual circumstances are present, courts depart from the general rule that scienter based on the core operations inference requires detailed allegations about the defendants' exposure to the type of information at issue. However, there are no such unusual circumstances here. For example, there are no factual allegations about how any Defendant interpreted or reacted to the Rat Study data or the FDA's request for bi-monthly updates on the data during the Class Period. The FDA's opinion did not characterize the data as suggesting a risk in humans. And, as pled, Defendants only learned of the FDA's opinion on the Rat Study data two days before the September 16, 2010 Advisory Committee meeting. Further, while the FDA's March 2008 request for bi-monthly updates was unusual, there are no facts pled to infer that each Defendant should have known about these updates, that they were unusual, or that the updates suggested a risk to humans (or even to the NDA). In sum, the facts alleged do not demonstrate that there was a red flag that Defendants knew or deliberately disregarded when they chose to speak about lorcaserin's safety.

Arguably, the Complaint plausibly shows that Defendant Lief and Defendant Anderson knew about the Rat Study data by March 12, 2009 and September 18, 2009, respectively. [*See* ¶97 (Lief's explaining that he is "encouraged by the overall emerging [risk/benefit] profile" because of ". . . . the preclinical studies that was [*sic*] done, all the animal studies that have been completed. . . . "; ¶128 (Anderson stating, ". . . . all of the data that we now need for this NDA. We have favorable results on

everything that we've compiled so far.").] Viewed holistically with other facts alleged, Lief's statement was sufficiently specific and Anderson's statement was sufficiently sweeping to attribute knowledge of the Rat Study to them. Therefore, the question for Defendants Lief and Anderson becomes whether each knew their "statements were false, or was consciously reckless as to their truth or falsity." *Gebhart*, 595 F.3d at 1042. The Court is not persuaded.

As currently pled, the Court finds it more plausible that Defendants Lief and Anderson knew about the Rat Study data and reasonably believed the results to be positive with regard to what the study was designed to test. Namely, "the potential risk that drug candidates may be toxic or cause cancer ***in humans***." [*See, e.g.,* ¶¶86, 89, 92, 99, 100, 123, 138, 159 (emphasis added).] The facts alleged do not show a nexus between the increased tumors found in the Rat Study to human use or risk. For example, there are no allegations that, during the Class Period, anyone suspected that the cancerous tumors found in the rats resulted from dosage amounts that were scientifically relevant to human use. Instead, the Complaint alleges that Arena promptly notified the FDA in March 2008 about the rat data, and that in response, the FDA did not halt lorcaserin's ongoing human clinical trials. This makes it more plausible that Arena's reporting to the FDA did ***not*** concern any suspected risk in humans. There is nothing to suggest that Lief or Anderson should have known the Rat Study data could negatively impact lorcaserin's safety profile or its NDA timeline. There is nothing to suggest that it would have been unreasonable for Lief and Anderson to interpret the Rat Study results as favorably contributing to lorcaserin's safety profile for humans and NDA. Therefore, under the facts alleged, the omissions about which Plaintiff complains do not raise an inference of scienter.

B. Falsity

As stated above, the Complaint fails to plead that Defendants' representations about the "end-of-review" meeting with the FDA in December 2010 were false or misleading. However, because the Court finds that the Complaint does not meet the

requisite pleading standard to allege sceinter, it does not reach Defendants' additional arguments as to falsity here.

Should Plaintiff choose to amend, he is directed to better identify which statements within the block-quotes provided he believes were false and misleading when made and why. Further, the Court encourages Plaintiff to narrow the scope of his alleged false and misleading statements to include only statements for which Defendants, under a different set of facts, may have had a duty to disclose information about the Company's preclinical studies. [*See* ¶¶97, 99, 110, 123, 128, 138, 156, 159, 173.] Despite this guidance, the Court makes no findings as to duty to disclose at this time.

IV. CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss [Doc. Nos. 44, 45] is **GRANTED WITHOUT PREJUDICE** to Plaintiff filing an amended complaint on or before **April 25, 2013**.

As the Court did not find it necessary to rely on the materials complained of in Plaintiff's Motion to Strike, the Motion [Doc. No. 47] is **DENIED as MOOT**.

IT IS SO ORDERED.

DATED: March 28, 2013

CATHY ANN BENCIVENGO
United States District Judge